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PCT/KR2004/001891

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCTA9407-11	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/KR2004/001891</b>	International filing date( <i>day/month/year</i> ) <b>27 JULY 2004 (27.07.2004)</b>	Priority date ( <i>day/month/year</i> ) 06 AUGUST 2003 (06.08.2003)	
International Patent Classification (IPC) or national classification and IPC  <b>IPC7 A61K 38/18</b>			
Applicant  <b>CJ Corp. et al</b>			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand  <b>02 FEBRUARY 2005 (02.02.2005)</b>	Date of completion of this report  30 MAY 2005 (30.05.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  LIM, Hea Joon  Telephone No. 82-42-481-5600

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001891

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☒ This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☒ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished

- ☐ the description:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the claims:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the drawings:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001891

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

Claims 1-6 of this invention relate to a formulation of albumin-free EPO comprising hydroxyethyl starch or hydroxyethyl starch and amino acids

The following document have been considered for the purpose of this report:

D1= US 6,586,573 B1, Jul. 1, 2003.

D2= Cryobiology, 2002, Vol. 45, No. 2, pp. 153-166.

#### 1. Novelty

Claims 1-6 of this invention relate to a formulation of albumin-free EPO comprising hydroxyethyl starch or hydroxyethyl starch and amino acids.

Document D1, which has been published prior to the filing date of the present application, discloses a formulation of albumin-free Factor VIII comprising hydroxyethyl starch or hydroxyethyl starch and amino acids, which is different from those of this invention in terms of protein of interest for formulation. Therefore, the subject matter of claim 1-6 is considered to be novel [PCT Article 33(2)]

#### 2. Inventive Step

The object of this invention and D1 have the same object of not containing albumin as a stabilizing agent for protein formulation. Also, the technical composition of this invention is similar to those of D1 such as protein of interest, amino acids and 0.1-10% hydroxyethyl starch compared to 2-6% in D1. But D1 utilized hydroxyethyl starch as a bulking agent, whereas this invention utilized it as a stabilizing agent. It has been known in the prior art that hydroxyethyl starch has stabilizing effect for freezing the protein without losing the activity, as described in D2. Thus it is not surprising selecting hydroxyethyl starch as stabilizer for EPO. But it have to be noted that the stabilizer and the resulting effect could be varied among the proteins according to physical and biochemical properties of proteins to be formulated. Thus, the effort to select stabilizer and to determine the stabilizing effect of hydroxyethyl starch should be appreciated as a surprising technical effect.

Therefore the subject matter of claims 1-6 is considered to involve an inventive step within the meaning of Article 33(3) PCT.

#### 3. Industrial applicability

The subject matter of claims 1-6 is considered to be industrially applicable. [PCT Article 33(4)]

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